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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,441	10/28/2003	Nobuhiko Ozaki	61352-055	8924

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/694,441	Applicant(s) OZAKI ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is drawn to a method for immobilizing a cell, however are rendered vague and indefinite for reciting "the step of exposing" and "followed by development" because it is unclear what is being exposed to what, and what is being developed.

Claim 9 is rendered vague and indefinite because it is unclear what the "detrimental constituent" is detrimental to.

Claim 10 is rendered vague and indefinite because it is unclear if the recited steps of immobilizing are in addition to, or rather than, the step (b) of claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1651

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jimbo in view of Yanagimoto et al. (US 5496584 A).

Applicant claims a method for immobilizing a cell onto a desired region of a substrate's surface, the method comprising (a) forming a masking layer on the substrate surface that is not in the desired region; (b) immobilizing cells by contacting a solution of cells with the substrate surface and masking layer; and (c) adjusting the pH of the solution such that the masking layer will separate from the substrate without loss of cell activity. The solution is a culture medium; and step (a) comprises forming the masking layer on the substrate and removing portions from the desired region. The masking layer has photosensitivity, and removing the layer comprises exposing the layer in one of the desired regions or the undesired regions, followed by development. The pH is elevated in step (c), to about 7.9 – 8.1, is adjusted by concentrating the CO₂ in the ambient atmospheres of the cell solution; or by adding a pH adjusting agent to the cell solution. The method further comprises heating the masking layer to a temperature that is higher than the boiling point of a detrimental constituent present in the masking layer, before

Art Unit: 1651

step (b); and the cells are immobilized by a material comprising any one of a cell adhesive protein, a positively charged polymer or a polymer with a strong basic functional group.

Jimbo teaches a method wherein cells are immobilized onto a substrate wherein a polyimide film (material with photosensitivity) is first applied to a substrate (p.804) and a solution of cells is applied thereafter (p.805). The solution of cells is a culture medium, and the cells are immobilized with polylysine and laminin (a positively charged polymer and cell adhesive protein) (p.805). The film (masking layer) is removed after the cells are immobilized (p.806).

Jimbo does not teach the method wherein the polyimide film (masking layer) is removed by adjusting or elevating the pH of the cell solution. However, at the time of the claimed invention, it was known in the art that polyimide films can be removed with alkaline solutions (or by increasing the pH level). In support, Yanagimoto teaches removing polyimide films by treating the substrate with an alkaline solution (or by increasing the pH) (col.1 line 62-67). Thus, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice (as evidenced by Yanagimoto) to remove the polyimide layer of Jimbo by increasing pH with a reasonable expectation for successfully immobilizing the cells of Jimbo.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 3, 2006
AU 1651

A handwritten signature in black ink, appearing to read 'RDAB', is positioned above the printed name of the examiner.

RUTH A. DAVIS
PATENT EXAMINER